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General Secretariat

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## **MEETING DOCUMENT**

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From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)

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Subject:	Working Party on Public Health on 06-07 March 2023 - Flash from the Presidency
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Delegations will find attached the Presidency Flash for the meetings of the Working Party on Public Health on 06-07 March 2023.

The draft agenda is set out in CMs 1856/23 and 1859/23.

# Swedish Presidency Flash

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## Meeting of the Working Party on Public Health

**Monday the 6<sup>th</sup> of March 2023  
10:00-13:00 & 14:30-18:30**

**&**

**Tuesday the 7<sup>th</sup> of March 2023  
10:00-13:00 (attaché format)  
14:30-18:30**

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Dear colleagues,

A warm welcome to this week's Working Party on Public Health!

The meeting will take place between 10:00-13:00 and 14:30-18:30 on the 6<sup>th</sup> of March, as well as 10:00- 13:00 (attaché format) 14:30-18:30 on the 7<sup>th</sup> of March. The agenda of this meeting will be continuing the examination of the EHDS proposal.

- Examination of the first compromise for Chapter I
  - Examination of Articles 1 and 2 (2) letter o, u, v, x, aa, ab, ac, ad and ae
- Continuing the examination of the first compromise for Chapter IV

- Presentation by The European Medicines Agency (EMA).

As an introduction and before the discussion on Articles 48 and 49, EMA will present, within the context of the EHDS, how the timely access of secondary health data is critical for its role, and to provide delegations with the opportunity to ask questions.

- Examination of Articles 48 and 49

- **Continuing the discussion on specific topics related to the secondary use**

- Specific topics to be discussed:
  - The scope and the definitions on health data holder in Article 2(2)(y)
  - The scope and the definition on health data user in Article 2(2)(z), including the scope on applicant for a data permit in Article 45(1) or a data request in Article 47(1)

To facilitate the discussion, we have prepared a discussion material, which you find below in this flash.

- **Mapping of the applicable legal bases and the interplay of natural persons rights**

- With a view to facilitate upcoming work and reaching mutual understanding the Presidency will present a mapping of the applicable legal bases in Articles 6 and 9 in the GDPR and the interplay to the rights of natural person in the same regulation regarding the secondary use of electronic health data.

Delegations will have an opportunity to provide feedback on the mapping (both during the meeting and afterwards in written comments).

- **Mapping of the data flow and the responsibility in relation to secondary use of electronic health data**

- With a view to facilitate upcoming work and reaching mutual understanding the Presidency will present a mapping of the data flow and the responsibilities regarding secondary use both in a national and in a cross-

border context. The mapping is especially related to Articles 45, 46, 47, 50, 52 and 66.

Delegations will have an opportunity to provide feedback on the mapping (both during the meeting and afterwards in written comments).

- **Presentation and examination of the first compromise for Chapter V to VIII**
  - Presentation of the first compromise for Chapter V to VIII
  - Examination of Articles 59, 60, 61, 62, 63, 64 and 65

## **CONTINUING THE DISCUSSION ON SPECIFIC TOPICS RELATED TO THE SECONDARY USE**

### **THE SCOPE AND DEFINITION OF HEALTH DATA HOLDER**

Article 2(2)(y) on the definition of health data holder is central for the secondary use of electronic health data. The health data holders are the entities that shall provide electronic health data to the European Health Data Space for secondary use.

The health data holder shall make the electronic health data it holds available upon request (a legal obligation). See Article 35B in the first compromise proposal.

The health data holder shall also inform about their dataset (also a legal obligation). See Article 35B in the first compromise proposal.

Micro enterprises could be excluded from these obligations, see Article 35B (8) in the first compromise proposal.

To facilitate the discussion the Presidency has prepared options. The options are based on comments and questions raised in the first reading of the text. Member States are invited to provide guidance on preferred options. Member states are also hereafter welcome to provide the Presidency with further comments regarding the definition.

#### **Option 1 – Current scope and definition of health data holder with a clarification that also social security is included**

Article 2(2)(y)

- **'health data holder'** means ~~any~~ natural or legal person, which is an entity or a body in the health or care sector, **including social security**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**
  - a) **the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**
  - b) **the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679** ~~non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;~~

Comment: This is a broad definition of health data holder and include all entities in the health and care sector, including the social security sector.

As we understand it, the definition as suggested in option 1, would include for example both private and public health and care providers, pharmaceutical companies, entities within social security, public institutions, and public sectors bodies with tasks in these sectors, including bodies that produce official statistics in these sectors, researchers, insurers, EMA and ECDC etc. See recitals 38 to 40 in the Commission's proposal.

The definition could also include tech companies and other companies when their perform within the health and care sector. For processing of personal electronic health data they need to act as a controller and not for example as a processor. Clarifications on this could be provided in the recitals.

## Option 2 – Narrowing the scope and definition of health data holder

Article 2(2)(y)

- **'health data holder'** means ~~any~~ natural or legal person, which is an entity or a body in the health or care sector, **excluding social security**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**
  - c) **the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or healthcare as well as care of elder and persons with disabilities or for public health, research, innovation, policy making,**

- official statistics, patient safety or regulatory purposes, in its capacity as a controller; or
- d) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679 non-personal data, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data;~~

Comment: By explicitly exclude social security and limit the care sector to only include care of elderly and person with disabilities option 2 would mean a narrowed definition of health data holder.

### **Option 3 – other amendments**

- Please provide us with other amendments and/or clarification on the scope of health data holder.

## **THE SCOPE AND DEFINITION OF HEALTH DATA USER AND APPLICANT**

The definition of health data user is central for the secondary use of electronic health data. The health data user are the entities who are able to process electronic health data for the secondary use purposes in Article 34. However, some purposes in Article 34 are reserved for public sector bodies and EUI, see Article 35(2).

The definition on health data user is closely connected to Article 45 and 47. Articles 45 and 47 states that a natural or legal person may submit a data access application and a data request respectively.

To facilitate the discussion the Presidency has prepared options. The options are result of comments and questions raised in the first reading of the text. Member states are invited to provide guidance on preferred options. Member states are also hereafter welcome to provide the Presidency with further comments regarding the definition.

### **Option 1 – Current scope and definition of health data user and the scope of applicant**

Article 2(2)(z)

- **‘health data user’ means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation**

Article 45(1) and 47(1)

- A natural or legal person may submit...

Comment: This is a broad definition of health data user and who may submit a data access application or a data request. It is important to keep in mind that the health data user needs to fulfil the requirement stated in Article 46 and 47.

## **Option 2 – Limiting the scope and definition of health data user and the scope of applicant**

Article 2(2)(z)

- **‘health data user’ means a natural or legal person within the jurisdiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52, who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation**

Article 45(1) and 47(1)

- A natural or legal person, **within the jurisdiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** may submit...

Comment: This option would limit the scope of potential health data users and applicants to ensure reciprocity and equal terms for the sharing of electronic health data for secondary use purposes in relation to the cross-border infrastructure. These entities would still need to fulfil the requirements in Articles 46 and 47 et cetera.

## **Option 3 – other amendments**

- Please provide us with other amendments and/or clarification on the scope of health data user and applicant.

## Written comments and text proposal on the first compromise for Chapter IV

- Written comments and text proposal to the Articles in first compromise proposal on Chapter IV would be appreciated at the latest on **Monday the 13<sup>th</sup> of March**.

In case you have any other points that you want to discuss under AOB, please don't hesitate to contact the Presidency and the Council Secretariat.

Please find our contacting details down below.

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## Sweden from A to Z – A piece of Swedish culture

It's time for yet another important tradition in Sweden; Midsommar (Midsummer). Midsummer takes place in June and is a celebration of the summer solstice, the longest day of the year. For many Swedes, this is a time to celebrate the beginning of the summer holidays together with friends and family.

So, if you want to celebrate Midsummer, what should you think about? Well, besides making (or buying if you do it the easy way) your own flower crowns, a maypole should also be created and raised during the day. The traditional singing and dancing around the maypole can then begin, which is greatly enjoyed by both kids and adults. Besides this, an important part of the day is to do different games such as "sack-jumping" (jumping as fast as you can with a big plastic bag around your legs), "egg on spoon" (having a spoon in your mouth with an egg on it, trying to reach the finishing line as fast as you can without breaking the egg) and "rubber boot throwing" (throwing a rubber boot as far as you can).



Of course, a perfect Midsummer should also contain a buffet with food such as differently flavoured herrings, sour cream, chive, potatoes, bread, egg, salmon and of course strawberries. In the evening there is often a grilled dish served of some kind. The food should be accompanying with schnapps. And as you by now know (if you read the flash about Crayfish-parties), singing breaks out when the schnapps glasses are refilled.



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